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⑤④ **Method and apparatus for installing a ventricular assist device cannulae.**

⑥⑦ A ventricular assist device cannula of a novel type including a blood drainage cannula tube (12) having a first end and a second end and a blood inlet cannula tube (11) having a first end and a second end with the tubes being attached together to form a sealed section having a convex outer surface (14). An opening is made in a heart, the blood drainage cannula tube (12) is inserted through the opening whereby the first end is disposed in a heart chamber and at the same time the blood inlet cannula tube (11) is inserted through the opening and also through the aortic valve so that the first end thereof is disposed in the aorta. At the convex surface (14), the ventricular assist device cannula is sutured to the heart to hold it in place and to prevent blood drainage therearound. The blood drainage cannula tube is attached to the inlet port of the pump and the second end of the blood inlet cannula tube is connected to the outlet end of the pump whereby this design and method of cannula requires only one opening into the heart instead of two.

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## METHOD AND APPARATUS FOR INSTALLING A VENTRICULAR ASSIST DEVICE CANNULAE

This invention relates to a ventricular assist device and, more particularly, to a ventricular assist cannula. The invention concerns a method of using it with left, right or bi-ventricular failure.

Ventricular assist devices (VAD) are gaining increased popularity for use in patients with left, right or bi-ventricular failure. Standard techniques require insertion of a cannula for drainage of the atrium or ventricle with insertion of a second cannula for reinfusion of blood into the aorta or pulmonary artery. This requires two cannulae for a single ventricular assist device and four cannulae for a bi-ventricular assist device. Physicians who have worked with ventricular assist device systems understand the space constraints and the potential kinking or twisting of these cannulae in the chest or at the skin insertion site. In addition, the theory is that the greater number of cannulae that are exteriorized, the greater the chance of transcutaneous contamination and infection.

It is an object of this invention to provide an improved ventricular assist cannula.

According to one aspect of this invention there is provided a ventricular assist cannula comprising: a blood drainage cannula tube having a first end and a second end; a blood inlet cannula tube having a first end and a second end; means for sealingly attaching an intermediate portion of the blood drainage cannula tube to an intermediate portion of the blood inlet cannula tube to form a convex outer surface; annular flexible suturing sleeve means extending around said convex outer surface for attachment to the interior periphery of an opening in a heart; and suture means for sealingly attaching said annular flexible suturing sleeve means to said convex outer surface.

Preferably, the annular flexible suturing sleeve means is dimensioned and configured for attachment to the periphery of a single opening in a heart.

According to another aspect of the invention, there is provided a method of installing a ventricular assist device cannula of a type including a blood drainage cannula tube having a first end and a second end and a blood inlet cannula tube having a first end and a second end, said method comprising:

making an opening in a heart;  
inserting the blood drainage cannula tube through said opening whereby said first end thereof is disposed in a heart chamber;  
inserting the blood inlet cannula tube through said opening and through the aortic valve so that said

first end thereof is disposed in said aorta;  
suturing said blood drainage cannula tube and said blood inlet cannula tube to said opening for sealing said opening and holding said cannula tubes in place;

attaching said second end of said blood drainage cannula tube to the inlet port of a pump; and attaching said second end of said blood inlet cannula tube to the outlet port of said pump. Thus with this design of cannula only one opening into the heart is needed instead of two.

According to another aspect of the invention there is provided a method of installing a ventricular assist device cannulae of a type including a blood drainage cannula tube having a first end and a second end and a blood inlet cannula tube having a first end and a second end, said method comprising:

making an opening in a heart;  
inserting the blood drainage cannula tube through said opening whereby said first end thereof is disposed in a heart chamber;

inserting the blood inlet cannula tube through said opening and through the pulmonic valve so that said first end thereof is disposed in said pulmonary artery;

suturing said blood drainage cannula tube and said blood inlet cannula tube to said opening for sealing said opening and holding said cannula tubes in place;

attaching said second end of said blood drainage cannula tube to the inlet port of a pump; and attaching said second end of said blood inlet cannula tube to the outlet port of said pump. Thus, with this design of cannula only one opening into the heart is needed instead of two.

Thus a device and method may be provided which requires making only one hole for each ventricular failure, instead of two as in conventional methods.

One embodiment of the present invention comprises a cannula which contains two lumens fabricated for use in ventricular assist device cannulation. A small lumen cannula may be mounted on a larger lumen cannula. The small diameter lumen cannula may extend beyond the larger cannula preferably by approximately 30 centimeters. This small diameter lumen cannula can be shortened to a desired length. The larger diameter lumen may provide drainage into the ventricular assist device and the small lumen may provide reflow from the ventricular assist device. The cannula may be placed through a purse-string suture in the left or right ventricle.

The larger diameter lumen (drainage lumen)

may be disposed in the ventricle while the smaller lumen cannula may pass through the aorta or pulmonic valve into the aorta or pulmonary artery. thus, for left ventricular assist device use, the double lumen cannula may be positioned as follows. the larger cannula is disposed within the left ventricle while the smaller cannulae passes through the left ventricle across the aortic valve into the aorta.

For right ventricular assist device insertion, the larger cannula may be disposed in the right ventricle and the smaller cannulae may pass through the right ventricle lumen across the pulmonic valve into the pulmonary artery. Exteriorization of these cannulas is basically in straight below the costal margins.

An advantage of the present invention is that it provides an improved method and apparatus for installing ventricular assist device cannulae.

Another advantage of the present invention is that it eliminates the need for making two holes in the heart to install a ventricular assist device cannula in either the right or left ventricle of a heart.

A further advantage of the present invention is that it provides an apparatus having blood inlet and blood drainage cannulae tubes for use with the above mentioned method which can easily be sealed to the inner periphery of an opening in a heart with a standard purse string suture.

Reference is now made to the accompanying drawings, in which:-

Figure 1 is a cross-sectional view through a human heart and showing the placement of a ventricular assist device cannula in the left ventricle and another in the right ventricle thereof;

Figure 2 is a cross-sectional view taken along line 2-2 of Figure 1 to show how the two cannula tubes are joined together and sealed so that an easy purse string suture can be made therearound for an effective seal; and

Figure 3 is a cross-sectional view of the heart as shown in Figure 1 but showing an alternate arrangement for installation of the apparatus of the present invention in the left and right sides of the heart.

Referring now to the drawings wherein like reference numerals designate identical or corresponding parts throughout the several views, Figure 1 shows a human heart having the apparatus of the present invention attached thereto. A ventricular assist device (10), shown in the present invention, has a small lumen inlet tube (11) attached to a larger blood drainage cannula tube (12) at the juncture shown in Figure 2.

These tubes (11) and (12) are made of standard flexible plastic material and in one embodiment thereof, as shown in Figure 2, a flexible plastic material is used to bond the two tubes (11) and (12) together and to fill in the openings around

the joint between the two so as to form a convex surface (14). It is important that this convex surface (14) be present because if a concave surface (such as if the substance (13) were not used to fill in between the tubes at the juncture thereof) then it would be difficult to seal around a concave surface at (14) by the use of a standard purse string suture (15).

The small lumen cannula tube (11) extends beyond the larger cannula tube (12) by approximately 30 centimeters. This small lumen cannula (11) can be cut shorter to a desired length by the surgeon using it. the larger drainage lumen cannula (12) provides drainage to the ventricular assist device (10) and the small lumen cannula tube (11) provides reflow from the ventricular assist device (10). The device (10) is placed through an opening formed in the heart at either the left ventricle or right ventricle as shown in Figure 1, or in both as shown in Figure 1.

The larger drainage lumen cannula tube (12) has an open end (16) and additional flow openings (17) positioned in the ventricle while the smaller inlet lumen cannula tube (11) passes through the aortic valve, in the case of the left ventricle, or through the pulmonary artery, the case of the right ventricle usage.

Therefore, for the left ventricular assist device usage, the double lumen cannula (10) is positioned by placing the blood drainage cannula tube (12), as shown in Figure 1, in the left ventricle as shown, while the blood inlet cannula tube (11), is placed through the left ventricle and across the aortic valve so that the open end extends into the aorta.

For right side ventricular assist device insertion, an opening is made in the right ventricle in the position shown in Figure 1 and the blood drainage cannula tube (12) is inserted therethrough to the position shown in Figure 1. while the smaller blood inlet cannula tube (11) passes through the right ventricle lumen across the pulmonic valve and until the open end thereof is in the pulmonary artery. Of course, a purse string suture is then made around the convex portion (14) of the device (10) by a rayon annular collar (15), or the like. The suture is completed by sewing the rayon collar (15) to the heart itself. Exteriorization of these cannulas is basically straight below the costal margins. A left ventricular assist device will require only one cannula device (10) as shown and, likewise, a right ventricular device would require only one cannula as well. A bi-ventricular assist device will, of course, require two of the devices (10) such as shown in Figure 1.

It will be understood of course that the devices (10) do not need to be attached precisely in the position shown in Figure 1. For example, Figure 3 shows an alternate positioning of the devices (10)

in the left and right sides of the heart.

Accordingly, it will be appreciated that the preferred embodiment disclosed herein does indeed accomplish the aforementioned objects. Obviously many modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that, within the scope of the appended claims, the invention may be practiced otherwise than as specifically described.

## Claims

1. A ventricular assist cannula comprising:

a blood drainage cannula tube having a first end and a second end;

a blood inlet cannula tube having a first end and a second end;

means for sealingly attaching an intermediate portion of the blood drainage cannula tube to an intermediate portion of the blood inlet cannula tube to form a convex outer surface;

annular flexible suturing sleeve means extending around said convex outer surface for attachment to the interior periphery of an opening in a heart; and suture means for sealingly attaching said annular flexible suturing sleeve means to said convex outer surface.

2. a method of installing a ventricular assist device cannula of a type including a blood drainage cannula tube having a first end and a second end and a blood inlet cannula tube having a first end and a second end, said method comprising:

making an opening in a heart; inserting the blood drainage cannula tube through said opening whereby said first end thereof is disposed in a heart chamber;

inserting the blood inlet cannula tube through said opening and through the aortic valve so that said first end thereof is disposed in said aorta;

suturing said blood drainage cannula tube and said blood inlet cannula tube to said opening for sealing said opening and holding said cannula tubes in place;

attaching said second end of said blood drainage cannula tube to the inlet port of a pump; and attaching said second end of said blood inlet cannula tube to the outlet port of said pump whereby this design of cannula only one opening into the heart is needed instead of two.

3. A method of installing a ventricular assist device cannulae of a type including a blood drainage cannula tube having a first end and a second end and a blood inlet cannula tube having a first end and a second end, said method comprising:

making an opening in a heart;

inserting the blood drainage cannula tube through

said opening whereby said first end thereof is disposed in a heart chamber;

inserting the blood inlet cannula tube through said opening and through the pulmonic valve so that said first end thereof is disposed in said pulmonary artery;

suturing said blood drainage cannula tube and said blood inlet cannula tube to said opening for sealing said opening and holding said cannula tubes in place;

attaching said second end of said blood drainage cannula tube to the inlet port of a pump; and

attaching said second end of said blood inlet cannula tube to the outlet port of said pump whereby with this design of cannula only one opening into the heart is needed instead of two.

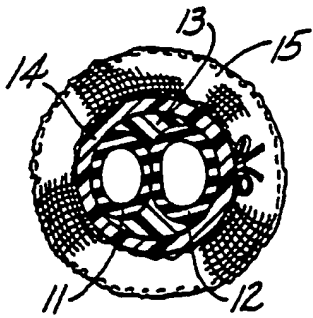
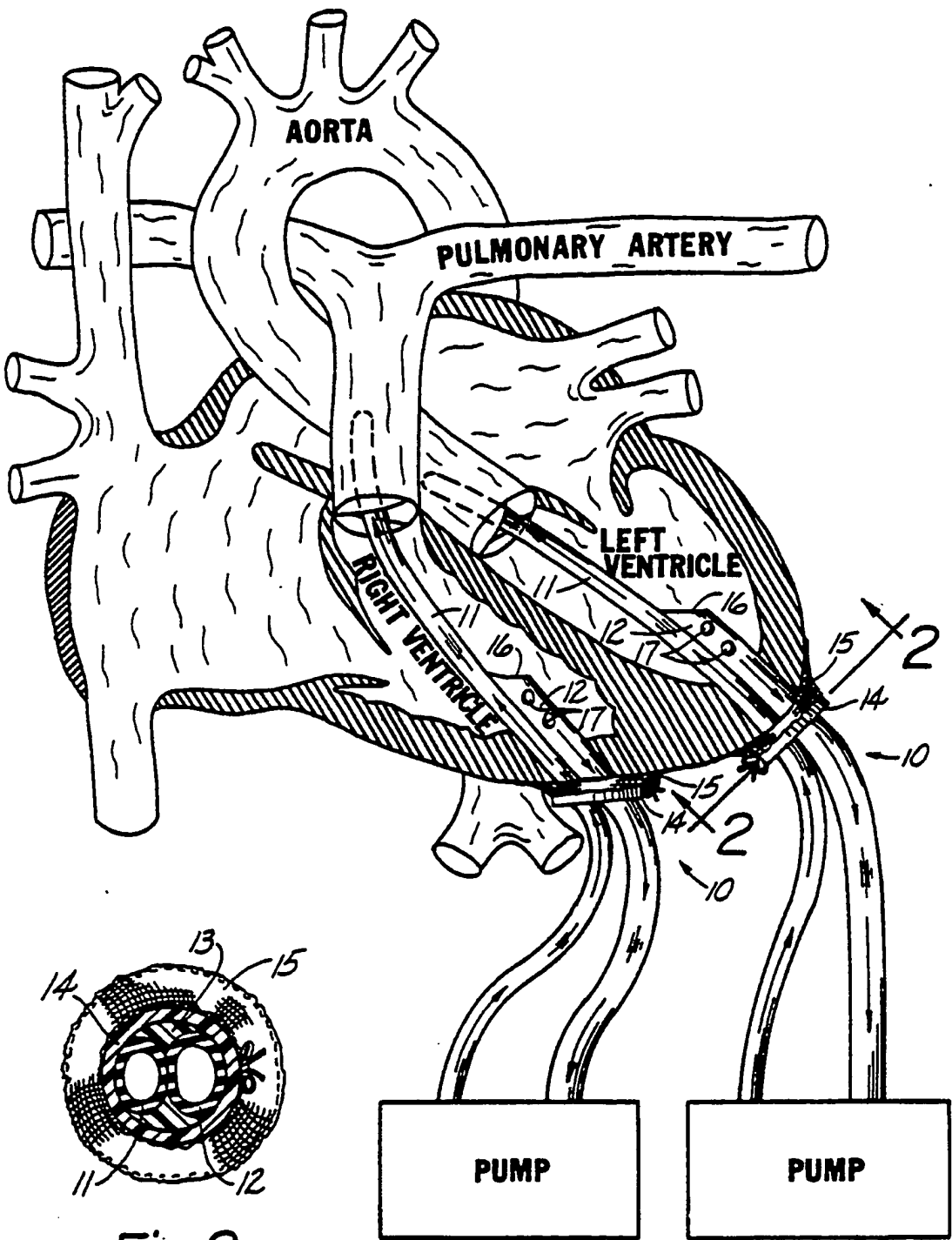
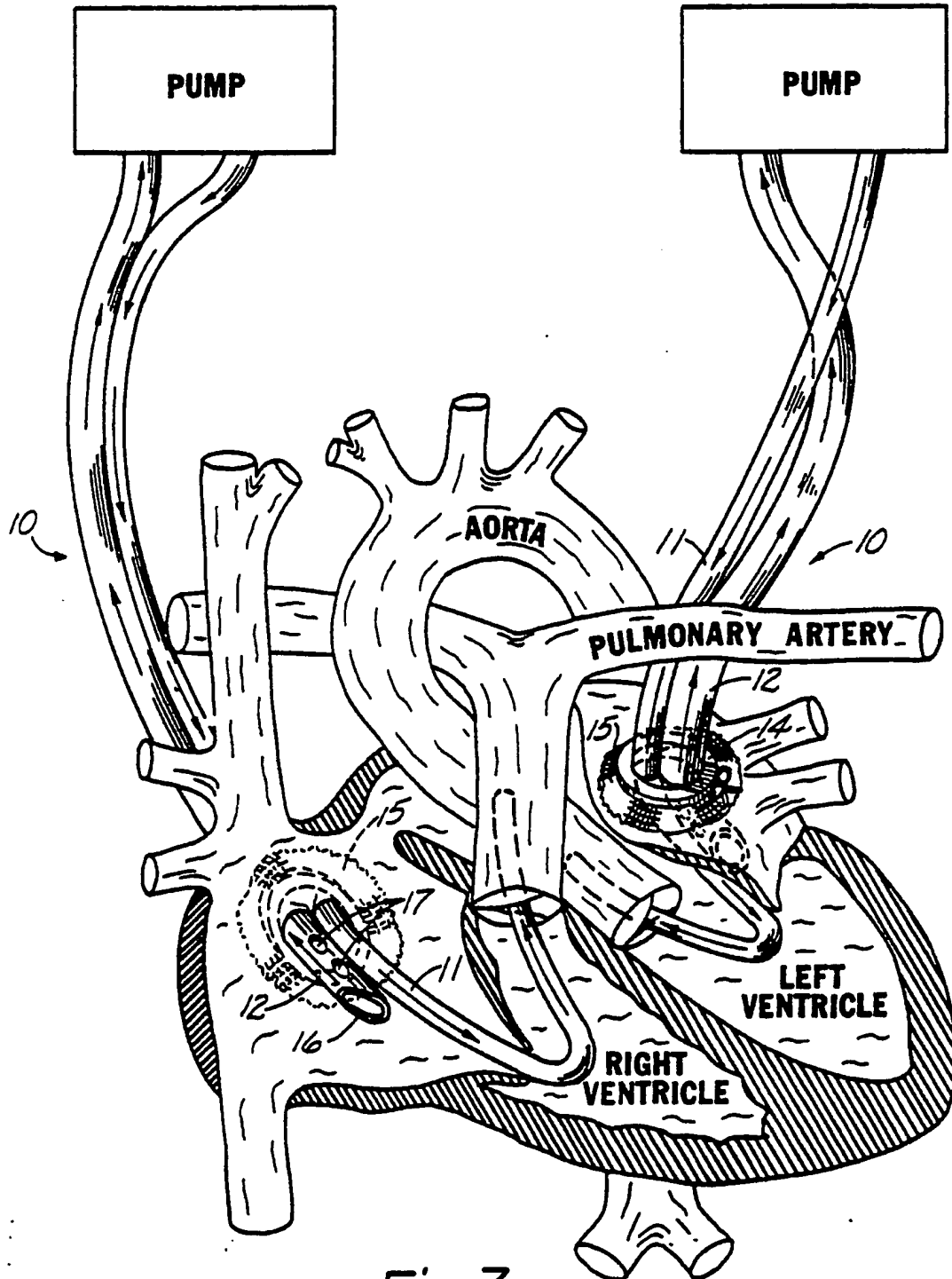


Fig. 2

Fig. 1

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*Fig. 3*

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European Patent  
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# EUROPEAN SEARCH REPORT

Application number

DOCUMENTS CONSIDERED TO BE RELEVANT			EP 90305700.8
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.)
A	<u>US - A - 4 309 994</u> (GRUNWALD) * Column 3, lines 14-57; fig. 4,5 * --	1	A 61 M 1/10 A 61 M 25/00
A	<u>US - A - 4 248 224</u> (JONES) --		
A	<u>US - A - 4 129 129</u> (AMRINE) -----		
The present search report has been drawn up for all claims			TECHNICAL FIELDS SEARCHED (Int. Cl.)  A 61 M 1/00 A 61 M 25/00
Place of search VIENNA		Date of completion of the search 18-09-1990	Examiner VELINSKY-HUBER
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons  & : member of the same patent family, corresponding document	